K070505

APR 5 - 2007

510(k) SUMMARY

This summary of Safety and Effectiveness is in accordance with the requirements of:

- Device Description

Krystal-X WiFi is a wireless digital X-ray sensor for intraoral radiography.

- Intended Use

The wireless digital X-ray sensor is intended to capture an intraoral digital X-ray for diagnostic purposes. The process is automatic; it continues by transmitting the digital image to a Personal Computer via WiFi. It requires additional components such as conventional X-ray tube and image capture software, currently available commercially.

- Summary of Substantial Equivalence Comparison

K061114 – WDS X-RAY, CEFLA

K050693 – ACCENT, AIR TECHNIQUES, INC.

K022953 – CDR Wireless, SCHICK TECHNOLOGIES

K053172 – KRYSTAL-X,

The proposed and predicated devices use similar components and are similar in design, technical characteristics and mode of operation. All the systems include a scintillator coupled to a digital image sensor, electronic circuits to analyze the digital image and a method of wireless transmission to transmit the digital image to a personal computer for viewing and further management of the file. The proposed and the predicated devices are substantially equivalent;

- WDS X-RAY is a wireless digital X-Ray sensor that captures an intraoral X-Ray, when exposed to X-Rays and transmits images via Bluetooth wireless technology, for diagnostic purposes..

- ACCENT is a wireless sensor very similar to WDS, which also transmits images via Bluetooth wireless technology.

- KRYSTAL-X is a conventional system, non-wireless, but identical in all other regards to **KRYSTAL-X WiFi**.

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- CDR Wireless is a wireless sensor that captures and transmits images via RF (Radio Frequency).

KRYSTAL-X WiFi is most similar in components to the original KRYSTAL-X, from our company, which was cleared by your agency on June 9, 2006.

The only difference is the method of communication between the sensor and the computer from a wired to a wireless interface. This modification is similar to the one Schick Technologies did when they introduced the CDR Wireless which modified their original CDR.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 5 - 2007

OWANDY, Inc.
% Mr. Claude Berthoin
President/Owner
Video Dental Concepts, Inc.
110 East Granada Boulevard, Suite 207
ORMOND BEACH FL 32176

Re: K070505
Trade/Device Name: Krystal-X WiFi
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH and MQB
Dated: March 29, 2007
Received: April 2, 2007

Dear Mr. Berthion:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K070505/S1

INDICATION FOR USE

Applicant: Owandy

510(k) Number (if known): K053172 (Krystal-X Standard)

Device Name: Krystal-X WiFi

Indication for use: The **KRYSTAL-X WiFi** digital system is used to provide instant digital images of human oral tissue and teeth without the use of a conventional x-ray film. It is used for diagnosis purpose, by dental practitioners. This is achieved by using the conventional x-ray tube (which is a third party device, not part of **Krystal-X WiFi**), and placing an electronic sensor in the patients' mouth instead of conventional film. The sensor, upon radiation exposure, automatically captures instantaneously and transmits the images by WiFi to the computer. The computer and imaging software (which is not provided by OWANDY) controls all aspects of image acquisition and image display, storage and printing. Additional software (after, and not part of, image capture software) is available on the market. They allow for enhancements such as zoom, contrasts controls, image inversion, and pseudo color renditions. The main advantages of this digital imaging system are: high definition, ensuring high-value diagnostics, and reduction of X-ray dosage. In no case, is it to be used directly by the patient. So, it is used exclusively in a healthcare specific environment. The WiFi device modification to our model **Krystal-X** in no way alters the indications for use of this device beyond what was originally approved in K053172.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070505

Prescription Use ✓